

## Standard Operating Procedure

**SOP131**

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Title: Protection of CBE Laboratories and Equipment from the Effects of 'Extreme' Cold Weather

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Location: CBE Laboratories at Holywell Park

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### 1. PURPOSE

The intent of this SOP is to describe procedure for mitigating the impact of cold temperatures and water ingress on CBE laboratory infrastructure and equipment that may arise from the adverse effects of 'extreme' external cold temperatures on site utility systems.

### 2. SCOPE

This SOP applies to the Centre for Biological Engineering Laboratories and the Cell Therapy Manufacturing Facility (CTMF) located in Area GH, Garendon Wing, Holywell Park. This SOP describes the procedure for monitoring external atmospheric temperatures during the winter months and for implementing emergency response procedures when external atmospheric temperatures exceed designated action limits.

This procedure follows recommendations documented in CTMF/CAPA001 and shall be reviewed annually or whenever any new site preventative measures are implemented by LU Facilities Management.

Note that emergency procedures for HTA relevant material are listed in CBE/HTA-MI-SOP010.

**The procedure MUST be implemented on the 1st November and monitoring maintained until at least the 28th February every year.**

### 3. RESPONSIBILITIES

#### **Responsible Person (RP) and/or Deputy/Quality Manager (QM)**

- RP shall check weather forecast data against designated Alert Limits.
- RP shall collect external temperature data and internal plant room temperature.
- QM shall analyse external temperature data, when forecast Alert Limit is exceeded.
- RP shall inform laboratory users when external temperature action limits are exceeded and consult with laboratory users to assess risk to ongoing projects before implementing emergency response procedures.
- RP shall inform the DSO, CBE Management Committee, LU Facilities Management when emergency response procedures are implemented.
- RP/QM shall initiate a CAPA procedure, as required.
- RP shall inform the DSO, LU Facilities Management or Loughborough University Security in the event of any incidences of water ingress to facilities.

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- RP/QM shall obtain the required permissions before allowing entry of personnel into waterladen laboratories.
- RP/QM with available members of the CBE Management and Safety Committee's shall develop phased recovery and contingency plans for recovery of facilities and work activities.
- QM/RP to activate or organise activation of smart key to the plant room on a weekly basis.

### **CBE Laboratory Users**

- Shall ensure that they are familiar with the procedures described in this SOP so that they are aware of the impact of emergency response procedures on any ongoing work within the CBE laboratories.
- Shall cooperate and assist the RP in implementing agreed emergency activities (e.g. relocation of materials, equipment etc.).

## **4. EQUIPMENT AND MATERIALS**

- Dataloggers (MSR 145) - Datalogger A (stored in the CBE office, to be moved to the Plant Room when required near extract AHU); Datalogger B (stored in the CBE office, to be moved to the Plant Room when required near inlet AHU); temperature monitoring system connected to the Facility Monitoring system (located in Gas Pod 2) temperature shown in the monitoring system in corridor.
- Waterproof Sheets for covering equipment.
- Bright torches to show work in the dark.

## **5. PROCEDURE**

### **Step 1: External Temperature Monitoring (from 1st Nov until at least 28th February every year).**

- 1.1. Place and set-up temperature Datalogger A and B in the Plant Room to measure internal temperature
- 1.2. Temperature is continuously monitoring external temperature outside the CBE (gas pod 2)
- 1.3. Set the data loggers to capture data every 15minutes
- 1.4. Monitor the BBC online short-range weather forecast daily, including weekends, at <http://www.bbc.co.uk/weather/le11>.
- 1.5. If the minimum temperature forecast for the next day is  $\leq 0^{\circ}\text{C}$  (ALERT LIMIT), then begin analysis of the temperature logger data as described in Step2

### **Step 2: Analysing the temperature logger data**

- 2.1. Capture the data from Dataloggers A, B and external gas pod probe. Chart the data from 3 dataloggers over a minimum 12 hour sampling period i.e. 18.00 – 06.00 hrs.

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- 2.2. Analyse the external temperature data (from Datalogger B) for trends. If two consecutive incidents of an external temperature within the range of  $\leq -5^{\circ}\text{C}$  to  $\geq -10^{\circ}\text{C}$  (ACTION LIMIT 1) are observed implement the **Emergency Protocol 1 only**.
- 2.3. If two consecutive incidents of an external temperature of  $-10^{\circ}\text{C}$  or lower (ACTION LIMIT 2) are observed, implement **Emergency Protocols 1 AND 2**.
- 2.4. If the external temperature Action Limits are NOT exceeded **no action is required**. Continue to analyse the data while the forecast predicts a temperature of  $\leq 0^{\circ}\text{C}$ .

### **Step 3: Emergency Protocol 1 (Action Level 1: protection from potential effects of cold temperatures and water ingress)**

- 3.1. Inform and warn all CBE laboratory users, CTMF staff and laboratory management.
- 3.2. Before implementing the protocol check with laboratory users/CTMF staff to assess the risk to ongoing projects and identify any mitigating actions to be taken during the day. The following actions shall always be carried out at the end of each working day when action limits have been breached, unless there are exceptional circumstances where the loss of work is not acceptable eg based on excessive cost or time recovery.
- 3.3. At the end of the working day: Check the location of the cryostorage banks. Make sure all CBE cryostorage banks are located in H-30 and H-31 (the dark room and the autoclave room), H34 and the CTMF cryostorage bank is located in H-08.
- 3.4. At the end of the working day: Switch off and unplug the following equipment:
  - All BSCs (CBE and CTMF),
  - All the flowcytometers and cover with plastic sheets (CBE).
  - The Cedex bio-analyser and cover with plastic sheets (CBE).
  - The ambr bioreactor and its BSC
  - The Biostation
  - Fluorescent microscope (H30)
- 3.5. At the end of the working day: Turn off the gas supply (supply side i.e. at the gas cylinder(s)) and turn off the heaters for CO<sub>2</sub> supply.
- 3.6. DO NOT switch off the following equipment but cover with plastic sheets:

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- All Incubators
- All Fridges/Freezers

- 3.7. At the start of the next day: Check and analyse the temperature data from the Plant Room (Datalogger A and B).
- 3.8. If two consecutive incidents of an external temperature of -10°C or lower (ACTION LIMIT 2) are observed, check the facility (CBE and CTMF) and the Plant Room for evidence of frozen pipes or water ingress. Check that the HVAC systems are functioning.
- 3.9. If evidence of frozen pipes, water ingress and/or HVAC malfunction is observed implement **Emergency Protocol 3**. If no evidence is observed implement **Emergency Protocol 2**.
- 3.10. If two consecutive incidents of an external temperature of -10°C or lower are **NOT** observed, there is no evidence of frozen pipes or water ingress in the Facility or Plant Room and the HVAC systems are fully operational, return equipment to operational state for the working day; returning to Step 3 at the end of the working day (i.e. maintaining Action Level 1).
- 3.11. At the start of the next day: Check and analyse the external temperature data (gas pod 2, reading from temperature monitoring system) according to Steps 1 and 2.
- 3.12. If the Action Limits 1 or 2 for the external temperature data (Datalogger B) are **NOT** exceeded, stand the facility down and return to the Normal State (Step5).
- 3.13. Continue monitoring the forecast data according to Step 1.

### **Step 4: Emergency Protocol 2 (Action Level 2: protection from potential water ingress)**

- 4.1. Disconnect all BSC flexible ducts (CBE and CTMF).
- 4.2. Cover all cryostorage banks with plastic sheets (CBE and CTMF).
- 4.3. At the start of the next day: Check and analyse the temperature data from the Plant Room (Datalogger A).
- 4.4. If two consecutive incidents of an external temperature of -10°C or lower (ACTION LIMIT 2) are observed, check the facility (CBE and CTMF) and the Plant Room for evidence of frozen pipes or water ingress. Check that the HVAC systems are functioning.
- 4.5. If evidence of frozen pipes, water ingress and/or HVAC malfunction is observed implement **Emergency Protocol 3**. If no evidence is observed maintain Action Level 2.

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- 4.6. If two consecutive incidents of an external temperature of -10°C or lower are **NOT** observed, there is no evidence of frozen pipes or water ingress in the Facility or Plant Room and the HVAC systems are fully operational, return equipment to operational state for the working day; returning to Step 4 at the end of the working day (i.e. maintaining Action Level 2).
- 4.7. At the start of the next day: Check and analyse the external temperature data (Datalogger B) according to Steps 1 and 2.
- 4.8. If the Action Limits 1 or 2 for the external temperature data (Datalogger B) are **NOT** exceeded, stand the facility down and return to the Normal State (Step 5).
- 4.9. Continue monitoring the forecast data according to Step 1.

### **Step 5: Facility 'Stand down' - Recovery to Normal Operational State**

- 5.1. Notify all CBE laboratory users, CTMF staff and laboratory management.
- 5.2. Reverse steps 3 and/or 4, as required, to return the facilities to Normal State.
- 5.3. Continue to monitor the forecast temperatures according to Steps 1 and 2.

### **Step 6: Emergency Protocol 3 (Action Level 3: protection after water ingress/flooding from burst pipes in the Plant Room)**

- 6.1. Inform the Loughborough University Facilities Management (LUFM) Helpdesk at x22-2121 (during working hours) or Loughborough University Security at x22-2141 (after hours).
- 6.2. Inform the DSO and obtain permission from LUFM ([fmhelp@lboro.ac.uk](mailto:fmhelp@lboro.ac.uk) or x22-2121) to enter the laboratory with the DSO.

**NOTE:** *A key to the Emergency Door in the CBE corridor shall be retained by the RP. This can be used, with permission of LUFM/Security, for out-of-hours access and/or if the swipe card access is not in operation.*

- 6.3. If permission to enter is granted, inform all laboratory users and arrange a time to meet available users at the Holywell site laboratory to help with any approved equipment removal.
- 6.4. Remove the cryostorage banks and contents of fridge/freezers and incubators to agreed temporary off-site locations (e.g., Containment Level 2 laboratories in Chemical Engineering and/or the Tissue Engineering Laboratory in the Wolfson School).
- 6.5. Develop a contingency plan to transfer essential CBE work activities to off-site locations (e.g., Containment Level 2 laboratories in Chemical Engineering and/or the Tissue Engineering Laboratory in the Wolfson School).

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### **Step 7: Recovery to Normal Operational State following implementation of Action Level 3**

- 7.1. When safe to enter the laboratory facilities (including the Office Area), inspect all facilities and remaining equipment. Make a list of all damage visible to the eye. Take photographic evidence of the damage if able.
- 7.2. Circulate the list to all laboratory users, CTMF staff, and CBE management personnel.
- 7.3. Implement cleaning and disinfection programme for laboratory facilities according to the appropriate local facility procedures (i.e. for CBE and CTMF laboratories).
- 7.4. Implement the Environmental Monitoring programme.
- 7.5. Reassess the damage to facility infrastructure and equipment.
- 7.6. Develop a phased recovery plan for the inspection, repair and/or servicing or replacement of damaged items and submit to the CBE Management Committee for approval.
- 7.7. Once approved by the CBE Management Committee, implement the recovery plan.
- 7.8. Transfer ongoing work activities from off-site locations (e.g., Containment Level 2 laboratories in Chemical Engineering and/or the Tissue Engineering Laboratory in the Wolfson School) back to the CBE.

## **6. DOCUMENTATION**

The following records are outputs of this SOP:

- (i) Temperature Data Trending Charts
- (ii) A CAPA shall only be initiated in the event a real emergency incident not for false alarms i.e. under Action Level 3.

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### SOP Version History

Version Reviewed	Date Revised/ Reviewed	Revision Summary	New Version Number
0	24.10.13	<p>This SOP is reviewed annually. It was confirmed with FM (Steve Caulfield) that no change has been made to the Plant Room specification. We shall start monitoring the CBE facility as planned.</p> <p>Reviewed by: P. Hourd/ A. Chandra</p>	1.0
1	28.10.14	<p>Minor editorial changes to incorporate new datalogger attached to the Facility Monitoring system</p> <p>Reviewed by P. Hourd/A. Chandra</p>	2.0
2	21.10.15	<p>Editorial changes. New equipment: (1) Cedex bioanalyser, (2) ambr bioreactors, (3) DasGip bioreactor, (4) CTMF cryostore unit added.</p> <p>Added reference to the HTA relevant material SOP.</p> <p>Reviewed by P. Hourd/F. Ahmed/A. Chandra</p>	3.0
3	26.10.16	<p>Editorial changes:</p> <ul style="list-style-type: none"><li>• New equipment (i) biostation, (ii) fluorescent microscope</li><li>• Removal of CTMF quality system</li><li>• FM Contact changed to <a href="mailto:fmhelp@lboro.ac.uk">fmhelp@lboro.ac.uk</a></li></ul> <p>Reviewed by A. Chandra/ N. Medcalf/ C. Kavanagh</p>	4.0
4	1.11.17	<p>Editorial changes:</p> <ul style="list-style-type: none"><li>• New equipment (i) ICellis nano (ii) Prodigy bioreactor</li></ul> <p>Additional change is the location of the dataloggers. Reviewed by A.Picken/ K.Sikand</p>	5.0

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5	01/11/19	Changes to the list of equipment to cover with tarpaulin. Removed :- AFM Das Gip Bioreactor I Cellis Nano Prodigy Bioreactor Added :- ADT machines Equipment in central bay in H34 Location of data loggers has been changed – two in plant room and probe in gas pod 2. Reviewed by K.Sikand.	6.0
6	08/10/20	Added under responsibilities to activate the smart key for access to the plant room, this should be carried out every week. Under equipment to be covered removed the compact selects in the CTMF and H21. Reviewed by K.Sikand/C.Kavanagh.	7.0

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